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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/781,069

02/18/2004

Armin Meinzer

100-8388C

1856

1095

7590

11/14/2006

EXAMINER

CHANNAVAJALA, LAKSHMI SARADA

NOVARTIS

CORPORATE INTELLECTUAL PROPERTY

ONE HEALTH PLAZA 104/3

EAST HANOVER, NJ 07936-1080

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 11/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/781,069

Applicant(s)

MEINZER ET AL.

Examiner

Lakshmi S. Channavajjala

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 12-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Receipt of response and notice of appeal dated 9-15-06 is acknowledged.

Claims 1226 are pending in the instant application.

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

### ***Response to Arguments***

Applicant's arguments, see pages 1-3, filed 9-11-06, with respect to the rejection(s) of claim(s) 12-26 under 35 USC 103(a) as being unpatentable over Hauer et al have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made as follows:

### ***Double Patenting***

Claims 12-26 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,432,445 ('445) in view of US 5,962,019 ('019). '445 claim a capsule comprising cyclosporin, a polyoxyethylene sorbitan fatty acid ester, a reaction product of a natural or hydrogenated castor oil and ethylene glycol and ethanol. Component C of the '445 capsule reads on the instant surfactant. '445 capsules do not contain the polyethylene glycol of the instant claims.

'019 teach hard gelating capsules comprising cyclosporin formulations (abstract, col. 3 L 10-25). '019 teaches that the compositions contain an orally acceptable vehicle

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comprising at least one alkanol solvent constituting an alkanol having 2 to 3 carbon atoms and a co-solvent selected from fatty acids and diols (col. 4, L 28-41). Among the diols, '019 teach the claimed polyethylene glycols (col. 5, L 1-25 and examples in col. 8-10). '019 further teach incorporating at least one surfactant, such as polyoxyalkylene surfactant having an HLB value of 5 to 20 or preferably 8 to 16. Thus, both '445 and '019 are directed to cyclosporin containing capsule formulations. It would have been obvious for one of an ordinary skill in the art at the time of the instant invention to include polyethylene glycol, of '019 in the cyclosporin composition of '445 as a co-solvent for the lower alkanol solvent of '445 because '019 teach that the polyethylene glycol co-solvents adsorb water molecules, which may be present in the formulations thereby reducing the possibility for precipitation of the cyclosporin from the formulations, and also impart desirable properties such as viscosity, stability etc. Accordingly, a skilled artisan would have expected to achieve greater stability of the composition of '445 by incorporating the PEG of '019.

Claims 12-26 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 6,767,555 ('445) in view of US 5,962,019 ('019).

'555 claim a capsule comprising cyclosporin, a polyoxyethylene sorbitan fatty acid ester, a reaction product of a natural or hydrogenated castor oil and ethylene glycol and ethanol. Component C of the '555 capsule reads on instant surfactants. '555 capsules do not contain the polyethylene glycol of the instant claims.

'019 teach hard gelating capsules comprising cyclosporin formulations (abstract, col. 3 L 10-25). '019 teaches that the compositions contain an orally acceptable vehicle comprising at least one alkanol solvent constituting an alkanol having 2 to 3 carbon atoms and a co-solvent selected from fatty acids and diols (col. 4, L 28-41). Among the diols, '019 teach the claimed polyethylene glycols (col. 5, L 1-25 and examples in col. 8-10). '019 further teach incorporating at least one surfactant, such as polyoxyalkylene surfactant having an HLB value of 5 to 20 or preferably 8 to 16. Thus, both '555 and '019 are directed to cyclosporin containing capsule formulations. It would have been obvious for one of an ordinary skill in the art at the time of the instant invention to include polyethylene glycol, of '019 in the cyclosporin composition of '555 as a co-solvent for the lower alkanol solvent of '555 because '019 teach that the polyethylene glycol co-solvents adsorb water molecules, which may be present in the formulations thereby reducing the possibility for precipitation of the cyclosporin from the formulations, and also impart desirable properties such as viscosity, stability etc. Accordingly, a skilled artisan would have expected to achieve greater stability of the composition of '555 by incorporating the PEG of '019.

### ***Claim Rejections - 35 USC § 103***

Claims 12-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,342,625 to Hauer et al (Hauer) in view of US 5,962,019 ('019) to Cho.

Hauer teaches cyclosporin comprising pharmaceutical compositions in the form of microemulsion pre-concentrates and that are filled in hard gelatin capsules (abstract,

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examples, col. 29, lines 11-14). Examples in col. 26-29 are directed cyclosporin formulation, which include surfactants Cremophor RH 40, which is described as a reaction products of hydrogenated or natural vegetable oil and ethylene glycol, with an HLB value of 14-16. Thus, the surfactant of Hauer meets the claimed surfactant component. Hauer also teaches composition comprising propylene glycol and ethanol that read on the claimed lower alkanols (col. 18, last paragraph to col. 19, 1<sup>st</sup> paragraph). The pre-concentrate compositions of Hauer are free of water and form spontaneous emulsions (col. 5, lines 57 through col. 6, lines 35) and hence meet the claims 22, 23 and 26. Hauer teaches various amounts of cyclosporin in the examples that is within the claimed ranges (claim 16). Not all of the compositions of Hauer contain additional oils and the claimed lower alkanols.

Hauer fails to teach polyethylene glycol in combination with the lower alkanols.

Cho teaches hard gelating capsules comprising cyclosporin formulations (abstract, col. 3 L 10-25). Cho teaches that the compositions contain an orally acceptable vehicle comprising at least one alkanol solvent constituting an alkanol having 2 to 3 carbon atoms and a co-solvent selected from fatty acids and diols (col. 4, L 28-41). Among the diols, Cho teaches the claimed polyethylene glycols (col. 5, L 1-25 and examples in col. 8-10). 'Cho teach incorporating at least one surfactant, such as polyoxyalkylene surfactant having an HLB value of 5 to 20 or preferably 8 to 16. Thus, both Hauer and Cho teach cyclosporin compositions comprising a surfactant and hydrophilic solvents, constituting analogous art. Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to include

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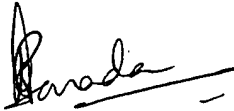
polyethylene glycol, of Cho in the cyclosporin composition of Hauer as a co-solvent for the lower alkanol solvent of because Cho teaches that the polyethylene glycol co-solvents adsorb water molecules, which may be present in the formulations thereby reducing the possibility for precipitation of the cyclosporin from the formulations, and also impart desirable properties such as viscosity, stability etc. Accordingly, a skilled artisan would have expected to achieve greater stability of the composition of Hauer containing cyclosporin by incorporating the PEG of '019. Further, optimizing the amount of solvents and co-solvents in the composition of Hauer with an expectation to achieve the desired solubility and optimum stability would have been within the scope of a skilled artisan. While Hauer does describe oils, the examples of Hauer do not necessarily contain oils and further instant specification does not define what "substantially free of oils" stands or the upper limit that meets the limitation. Therefore, Hauer still teaches compositions that are substantially free of oils, as claimed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.00 AM-4.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Lakshmi S. Channavaajjala', with a horizontal line underneath.

LAKSHMI S. CHANNAVAJJALA  
PRIMARY EXAMINER

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November 8, 2006